UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE KERYX BIOPHARMACEUTICALS, INC. SECURITIES LITIGATION	:	Civil Action No. 13-CV-00755 (KBF)

DEFENDANTS' MEMORANDUM OF LAW
IN SUPPORT OF THEIR MOTION TO DISMISS
PLAINTIFF'S CONSOLIDATED AMENDED COMPLAINT

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I. INTRODUCTION

This lawsuit concerns a clinical drug trial conducted by Defendant Keryx Biopharmaceuticals, Inc. ("Keryx" or the "Company") that sought to uncover a new cancer treatment, which would incorporate a drug known as perifosine. Clearly, such trials face long odds. Indeed, even when a drug shows good early results in clinical trials, those results do not guarantee ultimate success in the subsequent stages of the trial, which involve much larger patient populations.

Here, the perifosine trial initially showed promise. As discussed more fully below, an exploratory Phase 2 trial suggested that, in combination with other drugs, perifosine could prove effective in the treatment of patients with colorectal cancer, a particularly deadly form of cancer. Unfortunately, at the next phase of the exploratory trial, known as Phase 3, perifosine failed to live up to its earlier promise. When the Phase 3 results were revealed, the share price of Keryx fell.

Opportunistic shareholder strike suits like the present one have the potential to chill cancer research by seeking to reap a penalty for anything but guaranteed success in an industry where, unfortunately, successes are more the exception than the rule. Indeed, this is the second lawsuit premised on the very same perifosine trial and, in large part, is nothing more than a copycat of the earlier one that was dismissed. *Abely v. Aeterna Zentaris Inc.*, No. 12-Civ.-4711-PKC, 2013 WL 2399869 (S.D.N.Y. May 29, 2013). The previous action alleged almost identical claims against the co-developer of perifosine, Aeterna Zentaris, Inc. Ultimately, as explained below, the Court dismissed the action with prejudice. Despite this recent repudiation of the very theories upon which Lead Plaintiff relies and the ability to file an amended complaint, Lead

Plaintiff neglected to amend its claims substantively and, instead, retreads the same allegations and arguments rejected in the action filed against Aeterna Zentaris.

Boiled down to its basics, the Consolidated Amended Complaint (ECF No. 36) (the "CAC", cited herein as "¶ __") alleges in generalized terms that Defendants' statements that the Phase 2 results were "positive" and "statistically significant" were false and misleading based on nothing more than quibbles with the *design* of the Phase 2 trial and the disappointing results in Phase 3 of the trial. The CAC should be dismissed for 3 main reasons –

1. The CAC fails to plead falsity in conformance with the strict pleading requirements of the Private Securities Litigation Reform Act of 1995 (the "Reform Act"), 15 U.S.C. § 78u-4, *et seq.*[1] Multiple pages of block quotes followed by boilerplate conclusions about why those statements were allegedly false and misleading do not pass muster. *See, e.g.*, *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004). Additionally, criticisms of a trial's design or the statistical analysis used to interpret a trial's results do not show falsity and, therefore, cannot support a claim under the federal securities laws. *See, e.g., Kleinman v. Elan Corp.*, 706 F.3d 145, 154-55 (2d Cir. 2013).

2. The CAC falls short on scienter (or intent), an essential element of any Section 10(b) claim.[2] To support its flimsy scienter allegations, the CAC improperly relies on motives common to all executives, which cannot satisfy the element of scienter under the strict and heightened pleading requirements of the Reform Act. *See, e.g., ECA, Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009). The CAC also attempts to cast a suspicious light on certain stock sales

[1] *See infra* at 7-17.

[2] *See infra* at 17-22.

executed on Mr. Benstur's behalf, even though those sales were merely used to fund tax liabilities incurred when Mr. Benstur *increased* his holdings of Keryx stock during the putative Class Period. Unable to show scienter on the basis of motive and opportunity, the CAC also lacks any cognizable allegations that would suggest the Company or Mr. Bentsur committed any intentional or reckless wrongdoing with respect to the Phase 2 trial.

3. Finally, the CAC fails to plead loss causation adequately.[3] It alleges that Keryx's stock price dropped on the announcement that the Phase 3 trial failed, but makes no allegations that Defendants misled investors with respect to that phase. Instead, the alleged corrective disclosures relate solely to the methodology used in the Phase 2 study, which fails to demonstrate loss causation because that information was disclosed many months before the stock price dropped.

Defendants' Motion to Dismiss should be granted and the CAC should be dismissed with prejudice.

II. BACKGROUND

A. The Parties.

Keryx is a drug development company based in New York City devoted to the research and development of new "medically-important" drug treatments for patients with cancer or renal disease. (¶ 16) Defendant Ron Bentsur has served as the Chief Executive Officer of Keryx since May 20, 2009. (¶ 27) He was appointed as a Director of the Company on June 16, 2009. (¶ 17)

[3] *See infra* at 22-25.

Lead Plaintiff David A. Wilkinson represents that he is a Keryx shareholder. This putative class action has been filed on behalf of investors who purchased Keryx common stock between June 1, 2009 and April 1, 2012 (the "Class Period"). (¶¶ 1, 15)

B. The Process of Testing and Approving New Drugs in the U.S.

To market a drug in the United States, drug developers such as Keryx must first obtain the approval of the U.S. Food and Drug Administration ("FDA"). *See In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 195 (S.D.N.Y. 2008). In order to obtain approval, the drug's developer undertakes clinical trials, with each phase of the clinical trials designed to test different aspects of the drug's efficacy and safety. *See id*. at 195-96.

Clinical trials are typically conducted in three phases. *See id.* "Phase 1" tests the safety, dosage tolerance, and potential side effects. *See id*. at 196. "Phase 2" tests the drug on patients who suffer from the medical condition the drug is designed to treat. *See id*. If the Phase 2 results suggest the drug is safe and effective, then the drug moves to the next phase, "Phase 3." *See id.* Phase 3 tests the efficacy and safety of the drug in an expanded patient population. *See id.*

In a trial, statistical measures are taken to determine the drug's performance against certain benchmarks or "endpoints." (¶ 34) One data point, known as a "p-value," measures the results observed in the trial against the probability that the observed results occurred by pure chance. (¶ 33) Depending on the study, the developer of a drug trial may elect to adjust the p-values to reflect certain aspects of the trial. (¶ 40)

This case focuses on Phase 2 and Phase 3 of a clinical trial for the drug perifosine, which tested, among other things, the safety and efficacy of the drug in the treatment of colorectal cancer. (¶ 3) In a vain effort to state a claim, the CAC alleges generally and in conclusory

fashion that Defendants made public representations that lacked any reasonable basis because the Company failed to adjust the p-values it used to assess the Phase 2 trial. (¶ 5)

C. The Phase 2 Clinical Trial.

In 2007, Keryx began recruiting patients for an exploratory Phase 2 study of perifosine. (¶ 50) The Phase 2 trial was designed with two stages. (¶ 51) Under the protocol for the trial, Stage 1 would test perifosine (in combination with different chemotherapy agents) among patient populations with different cancer types. (*Id.*) If the interim analysis of the data showed a benefit to patients with a particular cancer, the study would expand at Stage 2 by adding patients suffering from that cancer type to determine if the positive results remained with an increased patient population. *See Placebo-Controlled Study of Perifosine + Single Agent Chemotherapy for Metastatic Cancer Patients* (the "Perifosine Protocol Synopsis") (Ex. A) (citations in the form of "Ex. __" refer to the exhibits attached to the Declaration of John A. Jordak, Jr., dated August 26, 2013, and filed contemporaneously herewith).[4]

As Stage 1 of the Phase 2 trial progressed, an interim analysis showed positive results for patients with colorectal cancer (¶¶ 58-59), which is the second leading cause of death from cancer in the United States. *See* National Cancer Institute, "General Information About Colorectal Cancer." (Ex. B) In line with the procedure outlined in the protocol, the trial – or treatment arms – populated with colorectal cancer patients expanded to include an additional 13 patients for Stage 2 of the Phase 2 study. (¶ 59)

[4] The Phase 2 protocol synopsis is publicly available on the ClinicalTrials.gov website which is maintained by the National Institute of Health, http://www.clincialtrials.gov/ct2/show/NCT00398879. The Court may take judicial notice of disclosures made in such publicly available documents. *See, e.g., Finn v. Smith Barney*, 471 Fed. Appx. 30, 32 (2d Cir. 2012); *Arista Records LLC v. Lime Grp. LLC*, 532 F. Supp. 2d 556, 571, n. 20 (S.D.N.Y. 2007).

D. The Phase 3 Clinical Trial.

On February 3, 2010, Keryx announced that it had reached an agreement with the FDA to conduct a Phase 3 trial of perifosine for patients with refractory metastatic colorectal cancer. (¶ 61) After almost two years conducting the Phase 3 trial, on April 2, 2012, Keryx announced that Phase 3 "did not meet the primary endpoint of improving overall survival versus capecitabine + placebo." (¶ 130). On the same day, Keryx's common stock declined $3.24 per share, to close on April 2, 2012 at $1.74 per share. (¶ 131)

E. The Securities Class Action Against Keryx's Co-Developer Was Dismissed With Prejudice.

Keryx licensed the North American rights to perifosine from another company called Aeterna Zentaris, Inc. pursuant to a License and Cooperation Agreement. (¶ 30) In exchange for the North American rights to perifosine, Keryx agreed to be jointly responsible for its development. (*Id.*) On June 15, 2012, a complaint virtually identical to the CAC was filed against Aeterna Zentaris in this Court under the federal securities laws, which contains claims based on the Phase 2 and 3 perifosine studies. On May 29, 2013, that case was dismissed with prejudice. *See Abely v. Aeterna Zentaris, Inc.*, No. 12-Civ.-4711-PKC, 2013 WL 2399869 (S.D.N.Y. May 29, 2013). The Court held, as is true here, that the complaint did not assert "actionable misstatements or omissions" and failed to "raise an actionable claim of securities fraud." *Id.* at *10.

III. APPLICABLE LEGAL STANDARDS

In order to succeed on their claims pursuant to Section 10(b), a plaintiff must show (1) a misstatement or omission of fact; (2) that is material; (3) made with scienter; (4) a connection between the misrepresentation or omission and the purchase or sale of a security; (5) reliance on the misstatement or omission; and (6) loss causation. *See George v. China Automotive Systems,*

Inc., No. 11-Civ.-7533-KBF, 2013 WL 3357170, at *2 (S.D.N.Y. July 3, 2013) (Forrest, J.) (citing *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta*, 552 U.S. 148, 165 (2008)).

Fed. R. Civ. P. 9(b) requires a plaintiff to plead allegations of fraud with particularity. To satisfy this requirement, the complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Anschutz Corp. v. Merrill Lynch & Co., Inc.*, 690 F.3d 98, 108 (2d Cir. 2012) (internal quotation marks omitted). In addition, the Reform Act requires a plaintiff in a shareholder class action to "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading" and to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(1), (2).

IV. ARGUMENT AND CITATION OF AUTHORITIES

The CAC should be dismissed for failure to meet the requirements for alleging a Section 10(b) claim. The CAC does not adequately allege (i) any false or misleading statements regarding the Phase 2 trial; (ii) the requisite scienter; or (iii) loss causation in connection with the claims alleged in the CAC. For these reasons, as explained below, the CAC should be dismissed with prejudice.

A. The CAC Does Not Adequately Allege Any False or Misleading Statement.

To state a cognizable claim under Section 10(b), a plaintiff must allege with particularity an actionable misrepresentation or omission of material fact. To comply with the Reform Act and withstand a motion to dismiss, a complaint must both (1) "specify each statement alleged to have been misleading" and (2) "the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1). As explained below, the CAC does neither and, for this reason alone, should be dismissed with prejudice.

1. Block Quoting Public Statements by Keryx and Summarily Concluding They Are False Does Not Meet the Reform Act's Stringent Particularity Requirements.

The CAC fails to allege with particularity any actionable misrepresentation or omission and, instead, takes issue with virtually every public statement Defendants made during the Class Period. (¶¶ 77-116, 121-29) Beginning with paragraph 77, the CAC confuses bulk with particularity by filling page after page with large block quotations, seemingly cut and pasted from press releases, SEC filings, presentations to investors, and investor call transcripts. (*Id.*) At the end of each block quotation, the CAC inserts a paragraph of almost uniform boilerplate, which contains the very same legal conclusion that Defendants' statements were somehow false and misleading. (¶¶ 84, 95, 116, and 129)

Those large block quotations and conclusory boilerplate do not come close to meeting the heightened pleading requirements of Rule 9(b) and the Reform Act. As the Courts in this District have repeatedly held, "Plaintiffs use of large block quotes from SEC filings and press releases, followed by generalized explanations of how the statements were false or misleading are not sufficient to satisfy the heightened pleading requirements" of the Reform Act. *Tabor v. Bodisen*, 579 F. Supp. 2d 438, 453 (S.D.N.Y. 2008); *see also Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004); *In re Sina Corp. Sec. Litig.*, No. 05-Civ.-2514-NRB, 2006 WL 2742048, at *6 (S.D.N.Y. Sept. 26, 2006); *In re Alcatel Sec. Litig.*, 382 F. Supp. 2d 513, 534 (S.D.N.Y. 2005).

In *Rombach v. Chang*, the complaint catalogued a series of defendants' press releases and then alleged that "various statements made therein were misleading because they failed to disclose or accurately represent the company's integration and liquidity problems." 355 F.3d at 172. The Court dismissed the complaint and held "plaintiffs must do more than say that the

statements in the press releases were false and misleading; they must demonstrate with specificity why and how that is so." *Id.* at 174.

In *In re Sina Corp.*, the complaint set "forth large block quotes taken from public statements made by the" defendants and from SEC filings, "followed by generalized explanations of why the statements collectively misled the plaintiffs." 2006 WL 2742048, at *6. The Court held that "[g]eneral allegations of this sort fail to satisfy the pleading requirements of Rule 9(b) and of the [Reform Act], which require a heightened degree of specificity." *Id.*

The CAC employs the very same impermissible pleading technique as the complaints criticized in the above cases. For example, paragraph 77 includes a large block quotation covering almost three pages of the CAC. The CAC never bothers, however, to specify what part of the three page quote, if anything, is allegedly false or misleading. Moreover, the CAC relies on the very same boilerplate allegations for why the numerous block quotes covering numerous topics are false or misleading. (¶¶ 84, 95, 116, and 129) As noted above, courts have held repeatedly that such a pleading technique fails to meet the requirements of the Reform Act. *See Rombach*, 355 F.3d at 174; *Tabor*, 579 F. Supp. at 453; *Sina*, 2006 WL 2742048, at *6; *Alcatel*, 382 F. Supp. at 534.

That faulty and fatal pleading pattern is repeated throughout the CAC. The CAC quotes liberally from press releases, SEC filings, and related earnings calls, in which Keryx reported financial information, without ever indicating what portion of these statements are false. (*See, e.g.*, ¶¶ 85-94). Moreover, many of the topics quoted could not possibly be alleged to be false or misleading. For example --

- "Keryx is committed to developing perifosine as a treatment that will provide a meaningful therapeutic value for patients living with refractory advanced colorectal cancer." (¶ 93)
- "We would be the first ones to admit that this study was not a large Phase 2 study, was 38 patients." (¶ 97)

For the aforementioned reasons, the CAC entirely fails to specify each statement alleged to have been misleading and why as required by the Reform Act and the CAC should be dismissed with prejudice. 15 U.S.C. § 78u-4(b)(1).

2. Disagreement with the Statistical Analysis and Scientific Methodology of a Clinical Trial Does Not Establish Falsity.

Even if it is assumed, *arguendo*, that the CAC had properly identified with specificity any alleged false statements (which, as shown above, it has not), the generalized criticisms of the perifosine study in the CAC with respect to why any statements are allegedly false or misleading have been repeatedly rejected. The CAC generally alleges that Defendants made "false and/or materially misleading" statements during the class period because Defendants characterized the results of the perifosine trial as positive and statistically significant. (¶¶ 84, 95, 116, 123, and 129) The CAC claims Defendants' statements were false and/or materially misleading due to the Company's "failure to adjust the P-values to account for the presence of multiplicity, hypothesis generation, and unplanned interim analyses in the Phase 2 study . . . ." (*See, e.g.*, ¶ 129; *see also id.* at 84, 95, 116, and 123)

"The Second Circuit has emphasized that in scrutinizing a section 10(b) claim, a court does not judge the methodology of a drug trial, but whether a defendant's statements about that study were false and misleading." *Abley v. Aeterna Zentaris Inc.*, No. 12-Civ.-4711-PKC, 2013 WL 2399869, at *7 (S.D.N.Y. May 29, 2013) (citing *Kleinman v. Elan Corp. PLC*, 706 F.3d

145, 154-55 (2d Cir. 2013)). In *Kleinman v. Elan Corp.*, the plaintiff alleged that defendants violated Section 10(b) by issuing an allegedly misleading press release concerning the results of a clinical trial for a drug under development. *See* 706 F.3d at 147. The press release had announced that the experimental drug demonstrated "statistically significant and clinically meaningful benefits" within a sub-group of patients taking part in Phase 2 of the trial. *See id*. at 149. Later, defendants issued another press release with additional information about the study, including that "the positive results were the result of backward-looking, post-hoc analysis . . . ." *See id.* at 150. After the release of this additional information, the price of the stock at issue dropped 42%. *See id.* at 150-51. The plaintiff alleged that defendants had knowingly withheld facts that were necessary to make the optimistic statements in the original press release not misleading. *See id.* at 152. The Second Circuit found plaintiff's real gripe, at its core, was "that Defendants were able to tout positive results only because they deviated from the established protocol . . . and changed the metrics by which data was analyzed." *Id.* at 154. The Second Circuit noted, however, that a Court's role was not to evaluate the statistical analysis used by defendants, and, therefore, it affirmed dismissal of the complaint. *See id.* at 154-55.

Similarly, in *In re MELA Sciences, Inc. Sec. Litig.*, the Court held that "Plaintiffs cannot premise a fraud claim upon a mere disagreement with how defendants chose to interpret the results of the clinical trial." No. 10-Civ.-8774-VB, 2012 WL 4466604, at *13 (S.D.N.Y. Sept. 19, 2012). In *MELA*, the complaint challenged the "publicly stated interpretations of the results of the clinical trial," including statements that the trial achieved "positive top line results" and "satisfied the specifications" of the protocol agreement. *Id.* Just as here, the complaint improperly concluded that "statements were misleading because they failed to disclose the utilization of an unsound statistical analysis . . . ." *Id.* Weighing that allegation, the Court

characterized the public statements regarding the trial results as "essentially no different than opinions." *Id.* To plead that an opinion was materially misleading, the Court instructed, "plaintiffs must allege with particularity provable facts demonstrating the statement of opinion is both objectively and subjectively false." *Id.* (citing *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 567 (S.D.N.Y. 2011)). In other words, the complaint must "show both that the [defendants] did not actually hold the belief or opinion stated, and that the opinion stated was in fact incorrect." *Id.* (internal quotation marks omitted). Ultimately, the Court found there was "no basis to conclude defendants characterized the results of the clinical trial in a manner inconsistent with what they believed to be the truth." *Id.* Based on that conclusion, the Court found the complaint did not "sufficiently allege defendants' statements throughout the Class Period regarding the results of the clinical trial were materially misleading." *Id.* Thus, the Court held that "defendants had no obligation to disclose the alleged flaws in the clinical trial." *Id.*

Based on the analysis in *Kleinman* and *MELA*, the CAC fails to plead falsity and should be dismissed with prejudice. The CAC merely quibbles with the statistical analysis Keryx used to evaluate the Phase 2 data. The CAC lacks any allegations whatsoever that Defendants' publicly expressed opinions about the Phase 2 results conflicted with the opinions Defendants subjectively held. Consistent with the Court's holding in *MELA*, Defendants had no obligation to disclose what the CAC alleges to be "flaws" in the clinical trial, namely, (1) the presence of multiplicity; (2) premature interim analyses; and (3) the inclusion of the original 25 patients in Stage 2. These are addressed in turn below. When examined closely, it is clear the study was hardly flawed, as alleged, and that, in any event, all of the allegedly flawed aspects were publicly disclosed.

a. The CAC Fails to Show Falsity Based on Multiplicity.

The CAC concludes that Keryx "omitted the material fact that Keryx's Phase 2 trial involved the multiple testing of different cancer treatments on a group of patients diagnosed with various types of cancer . . . ." (¶ 5) Similarly, in generalized terms, the CAC alleges that, "[d]uring Stage 1 of the Phase 2 study, the Company conducted multiple testing, treating patients diagnosed with at least seven different types of metastic cancer with one or more of eight separate chemotherapy regimens, and performing [sic] an unknown number of analyses of the data." (¶ 84; *see also* 95, 116, 123, and 129) According to the CAC, if statistical evaluation of a drug trial fails to take into account this type of "multiple testing" – also termed "multiplicity" – "unsubstantiated claims for the effectiveness of a drug ***may be made*** as a result of an inflated rate of false positive conclusions." (¶ 35) (emphasis added). In other words, the use of multiple research arms, and the failure to adjust p-values to account for that multiplicity, ***could*** – but not necessarily would – increase the potential for false positives and, by extension, affect the conclusions about a drug's efficacy.

This exact criticism of the perifosine trial was considered and rejected by the Court in *Aeterna*, which, as noted previously, concerned precisely the same Phase 2 trial at issue here. 2013 WL 2399869, at *2. In that case, the complaint alleged "that the use of multiple research arms gave defendants several opportunities to identify a statistically significant benefit, and heightened the likelihood of finding a false positive." *Id.* at *9. The Court found those baseless critiques all went "toward the design of the study and not to the existence of actionable misrepresentations or omissions." *Id.* at *10. Therefore, the allegations that the clinical trial, as designed, "invited false positives merely amount[ed] to a competing view of how the trial should have been designed, not an allegation of material misstatement or omission" and did not raise an

actionable claim. *Id.* The same conclusions should apply here and the CAC should be dismissed with prejudice.

The Ninth Circuit in *In re Rigel Pharmas., Inc. Sec. Litig.* also affirmed dismissal of a shareholder securities claim based, in part, on allegations that the design of a clinical trial resulted in p-values that "were not statistically significant." 697 F.3d 869, 877 (9th Cir. 2012). The Court characterized these allegations as "disagreements with the statistical methodology" and not allegations "about false statements." *Id.* at 878. The Court properly held that "[b]ecause Plaintiff does not allege that Defendants misrepresented their own statistical methodology, analysis, and conclusions, but instead criticizes only the statistical methodology employed by Defendants, Plaintiff did not adequately plead falsity with respect to statistic results." *Id*. at 879. Similarly, here, the CAC utterly lacks any specific allegations that Defendants misrepresented the statistical methodology, analysis, or conclusions of the Phase 2 trial. Instead, the CAC critiques the statistical methodology employed by Defendants. The CAC incorrectly concludes that, as a result of multiplicity in the trial, the Company should have adjusted the p-values. (¶¶ 84, 95, 116, 123, and 129). As the Courts held in *Aeterna* and *Rigel*, however, that criticism fails to plead falsity under the federal securities laws.

In any event, the presence of multiplicity was disclosed by the Company. The publicly available synopsis of the Phase 2 protocol expressly specified the categories of cancer that would be studied and the seven chemotherapy drugs that would be tested in combination with perifosine. (¶¶ 50-51) Additionally, as the CAC admits, the paper published in the *Journal Clinical Oncology* noted that "[t]he P values were not adjusted for the unplanned interim analyses or for the multiple comparisons (e.g., stratifications) because of the exploratory nature of the study design with small sample size." (¶ 118).

b. The CAC Fails to Show Falsity Based on Premature Interim Analyses.

As noted above, the CAC alleges that the statements at issue are purportedly false and/or materially misleading because the Company's statistical analysis allegedly failed to account for certain undisclosed facts. (¶¶ 84, 95, 116, 123, and 129) The second category of allegedly undisclosed facts includes the following: "[p]rior to the conclusion of Stage 1 of the Phase 2 study, the Company prematurely performed numerous unplanned interim analyses of the data." (¶ 84; *see also* ¶¶ 95, 116, 123, and 129) The CAC undercuts the allegation that the Company failed to disclose the interim analysis, however, because it also alleges that the Company "admitted that it had interposed unplanned interim analyses and data comparisons into the Phase 2 trial . . . ." (¶ 55) The CAC then attempts to explain this inconsistency away by listing additional facts related to the interim analyses that the Company allegedly should have disclosed as well. The CAC complains that Keryx neither "disclosed how many interim analyses or comparisons it performed . . . . Nor has Keryx disclosed the exact nature of these unplanned interim analyses . . . ." (*Id.*) After parsing through the inconsistent pleadings, it is clear that the Company disclosed the interim analyses.

As the Court held in *Aeterna*, "[p]ublic statements about clinical studies need not incorporate all potentially relevant information or findings, or even adhere to the highest research standards, provided that its findings and methods are described accurately." 2013 WL 2399869, at *6. The Court examined essentially the same public statements at issue here and found that the plaintiff did not "plausibly allege how the securities laws [could] obligate defendant to make additional disclosures about" Phase 2 of the perifosine clinical trial. Id. at *10. Although the Court acknowledged additional detail about the trial "may have been of interest to shareholders, or provided context to evaluate the findings on colorectal cancer," the Court also correctly

concluded that "relevance alone does not trigger the duty to disclose." *Id.* Here, the CAC clearly lacks any cognizable allegations that the Company's admissions of "unplanned interim analysis and data comparisons" were inaccurate. Thus, even if either of the changes made to the clinical trial or the overall methodology used fell below the standards normally expected in a clinical trial, the methodology was disclosed.

c. The CAC Fails to Show Falsity Based on Inclusion of the Original 25 Patients in Stage 2.

Finally, the CAC alleges that the Company failed to disclose its use of "25 stage 1 enrollees not only to generate a hypothesis about perifosine efficacy for mCRC patients, but also . . . to confirm that same hypothesis in Stage 2." (¶ 59) Based on that trial design, the CAC argues that the Company should have adjusted the p-values it applied to the Phase 2 study in order to provide a reasonable basis for Defendants' public statements. (¶¶ 84, 95, 116, 123, and 129) As examined above, this criticism of the clinical trial and its methodology cannot form the basis of a claim under the federal securities laws. *See, e.g., Klienman*, 706 F.3d at 154-55; *MELA*, 2012 WL 4466604, at *13. In any event, the Company disclosed this facet of the study design from the outset in the publicly available protocol synopsis. Specifically, the protocol synopsis disclosed that "[t]his is an exploratory phase 2, randomized placebo-controlled trial with stratification for disease and chemotherapy type. If there is any evidence of improved time to progression in any tumor type with any of the drugs to be evaluated, ***the initial study or component(s) of the study will be expanded*** to increase the certainty that this is an effect of perifosine." (*See* Ex. A (Perifosine Protocol Synopsis)) (emphasis added)

In *Aeterna*, the Court took notice of the applicable FDA guidance and found the complaint failed to allege with particularity how the approach taken in the perifosine trial materially contravened the guidance. *See* 2013 WL 2399869, at *8. Here, the CAC fails to

plead any authority to support its allegations that the Phase 2 study was flawed by the inclusion of the original 25 stage 1 patients in stage 2. The CAC does not point to a single source of FDA guidance that would require the Company to abandon the original 25 cancer patients – who showed positive results with perifosine – and continue with a new population of patients.

For the reasons described above, the CAC fails to plead falsity and should be dismissed with prejudice.

B. The CAC Does Not Adequately Allege Scienter.

The CAC should be dismissed with prejudice for the independent reason that it fails to allege scienter adequately. Failure to plead even one element of a 10(b) claim mandates dismissal. *See, e.g., Hart v. Internet Wire, Inc.*, 145 F. Supp. 2d 360, 366 (S.D.N.Y. 2001).

The Reform Act requires a plaintiff to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C.A. § 78u-4(b)(2). In other words, the scienter allegations "must give 'rise to a strong inference' of fraudulent intent." *Kleinman*, 706 F.3d at 152 (citing 15 U.S.C. § 78u-4(b)(2)(A)). In *Tellabs, Inc. v. Major Issues & Rights, Ltd.*, the Supreme Court set forth the proper test for determining whether a complaint sufficiently pleads a "strong inference" of scienter. 551 U.S. 308, 314 (2007). "To qualify as 'strong,' . . . an inference must be more than merely plausible or reasonable – it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Id.* at 309. In performing this comparative analysis, the court "must consider not only inferences urged by the plaintiff . . . but also competing inferences rationally drawn from the facts alleged." *Id.* at 314. Importantly, "omissions and ambiguities count against inferring scienter . . . ." *Id.* at 325.

In the Second Circuit, a complaint can satisfy the scienter element either (1) by alleging with particularity specific facts to show that defendants had motive and opportunity to commit fraud; or (2) by alleging with particularity specific facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness. *See, e.g., ECA, Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009). In either case, it is well-established law in this Circuit that "a plaintiff cannot base securities fraud claims on speculation and conclusory allegations." *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001).

Here, the CAC does nothing more than repeat conclusory allegations with respect to scienter. For example, the CAC alleges that "Defendants acted with scienter in that Defendants knew, or recklessly disregarded, that the public documents and statements issued or disseminated in the name of the Company (or in their own name) were materially false and misleading." (¶ 132) Additionally, the CAC states that "Defendants knew and/or unilaterally disregarded the false and misleading nature of the information that they caused to be disseminated to the investing public." (¶ 133) Such conclusory statements fail as a matter of law. *See, e.g., Rombach v. Chang*, 355 F.3d 164, 176 (2d Cir. 2004).

As examined below, beyond these conclusory allegations, the CAC makes a failed attempt to plead scienter by alleging facts based on motive and opportunity and intentional misconduct or severe recklessness.

1. The CAC's Motive and Opportunity Allegations Fail to Establish Scienter.

"Motives that are common to most corporate officers, such as the desire for the corporation to appear profitable and the desire to keep stock prices high to increase officer compensation, do not constitute" the requisite motive and opportunity for the scienter inquiry. *ECA, Local 134 IBEW Joint Pension Trust*, 553 F.3d at 198. Instead, "the 'motive' showing is

generally met when corporate insiders allegedly make a misrepresentation in order to sell their own shares at a profit." *Id.*

In an effort to plead motive, the CAC describes Mr. Bentsur's incentive compensation plan, which the CAC takes from Mr. Bentsur's employment agreement. (¶ 138) Without elaboration, the CAC presents certain aspects of the incentive compensation plan and then identifies shares in the Company Mr. Bentsur received pursuant to the plan. (¶¶ 138-40) The reader is left to presume that the CAC intends to imply that Mr. Bentsur had a general motive to inflate the Company's stock price because his employment agreement tied his compensation to the Company's share price. As the Second Circuit has held, however, "[i]f scienter could be pleaded on that basis alone, virtually every company in the United States that experiences a downturn in stock price could be forced to defend securities fraud actions." *Acito v. IMCERA*, 47 F.3d 47, 54 (2d Cir. 1995). Mr. Benstur's desire to increase his incentive compensation cannot, as a matter of law, form the basis for scienter allegations. *See, e.g., In re Take-Two Interactive Sec. Litig.*, 551 F. Supp. 2d 247, 273 (S.D.N.Y. 2008).

In another failed attempt to plead scienter, the CAC lists three occasions when Mr. Bentsur sold Keryx stock. (¶ 141) Insider sales of stock may be indicative of scienter only if the trades are unusual or suspicious in timing or amount. *See Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 587 (S.D.N.Y. 2011). Here, Mr. Benstur's sales of Keryx stock generally described in the CAC were neither. The alleged sales took place on, respectively, March 24, 2010; March 24, 2011; and January 3, 2012. (¶ 141) None of the sales took place shortly before the alleged October 2011 corrective disclosure or before the end of the Class Period on April 2012. For this reason alone, they cannot be indicative of scienter. *See Glaser*, 772 F. Supp. at 587.

The timing of the sales, however, does bear further explanation because the sales correspond to dates when Mr. Bentsur received shares through his compensation plan. As reflected on the relevant Form 4s, the stock transactions identified in the CAC were to cover taxes due on vesting and were executed without discretion. The filings explicitly stated that the sales were made "in order to satisfy Mr. Bentsur's income tax withholding obligation upon the vesting" of shares he received as part of his compensation plan. (Ex. C, D, and E) Such sales for tax reasons are not indicative of fraud. *See, e.g., In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 561 (S.D.N.Y. 2004).

Furthermore, as the public filings show, Mr. Bentsur actually increased his holdings in Keryx during the class period. This is inconsistent with the theory that he had a financial motive to commit wrongdoing or that Mr. Bentsur benefitted in a concrete and personal way from any alleged wrongdoing. Indeed, it supports the opposite inference. When a defendant increases his or her holdings during a class period, it serves as a "fact wholly inconsistent with fraudulent intent." *Id.*

2. The CAC Fails to Plead Intentional Misconduct or Recklessness.

As shown above, the CAC fails to allege scienter adequately on the basis of motive and opportunity. The analysis now turns to whether the allegations in the CAC demonstrate "strong circumstantial evidence" of Defendants' "conscious misbehavior or recklessness." *See ECA, Local 134 IBEW Joint Pension Trust*, 553 F.3d at 198. The answer is unequivocally no.

The CAC alleges that Keryx, because it controlled "the research and development of perifosine . . . intentionally directed the departures from the Phase 2 protocol and the interposition of interim analyses and comparisons . . . ." (¶ 136) The CAC alleges further that "Keryx would have known (or should have known) that the failure to adjust the *P*-values to account for the impacts of multiplicity, unplanned interim analyses, and hypothesis generation on

the Phase 2 results rendered its determination of the statistical significance of those results unreliable . . . ." (*Id.*)

The CAC has not sufficiently pled, however, that Defendants intentionally applied an improper statistical analysis or that Defendants exercised severe recklessness in adopting the statistical analysis chosen. The CAC attempts to use various articles and FDA guidelines to support its argument. However, not a single document cited in the CAC states that such adjustments "must" be made in all instances. To the contrary, the articles and guidelines do nothing more than urge caution in some cases where there appears to be multiplicity or the need for interim analyses. To plead scienter based on a recklessness theory, a complaint must plausibly allege that defendants "knew facts or had access to information suggesting that their public statements were not accurate." *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc.*, 531 F.3d 190, 194 (2d Cir. 2008). The CAC fails to plead or to cite any information that would have suggested to the Company or Mr. Bentsur that their public statements were not accurate or materially misleading.[5]

The CAC also contains a vague and conclusory allegation that Defendants engaged in intentional misconduct. The CAC alleges that "Defendants, by virtue of their receipt of information reflecting the true facts regarding Keryx, the control over, and/or receipt and/or modification of Keryx's allegedly materially misleading misstatements, were active and culpable participants in the fraudulent scheme alleged herein." (¶ 132) This allegation falls flat, however, because the CAC fails to identify specifically the "information reflecting the true facts regarding Keryx" that Defendants received. "Where plaintiffs contend defendants had access to contrary

[5] The CAC alleges that Mr. Bentsur recklessly sought to instill public confidence about the perifosine trial until the completion of the Phase 3 study for a separate drug called Zerenex. (¶ 137) This argument holds no water because the perifosine Phase 3 results were released almost one year before Zerenex's Phase 3 study came to a completion. *See* Keryx Biopharmaceuticals, Inc. 2012 10-K, Ex. F at 7.

facts, they must specifically identify the reports or statements containing this information." *See Novak v. Kansas*, 216 F.3d 300, 309 (2d Cir. 2000).

The CAC should be dismissed with prejudice because it fails to plead scienter adequately.

C. The CAC Does Not Adequately Allege Loss Causation.

"Loss causation 'is the causal link between the alleged misconduct and the economic harm ultimately suffered by the plaintiff.'" *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 172 (2d Cir. 2005) (quoting *Emergent Capital Inv. Mgmt., LLC v. Stonepath Group, Inc.*, 343 F.3d 189, 197 (2d Cir. 2003)). To establish loss causation, a complaint must do more than merely allege that a company's shares declined substantially in value after purchase. *See Dura Pharmas., Inc. v. Broudo*, 544 U.S. 336, 343 (2005). Instead, the complaint must allege "that the misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security." *Lentell*, 396 F.3d at 173. A complaint can make this showing "by alleging that the market reacted negatively to a 'corrective disclosure,' which revealed an alleged misstatement's falsity or disclosed that allegedly material information had been omitted." *In re AOL Time Warner, Inc. Sec. Litig.*, 503 F. Supp. 2d 666, 677 (S.D.N.Y. 2007).

Here, the CAC alleges two partial corrective disclosures, neither of which can provide a sufficient basis for the loss causation element. With respect to the first disclosure, the CAC alleges that an October 3, 2011 paper published in the *Journal of Clinical Oncology* disclosed that "Keryx had halted the originally planned Stage 1 of the Phase 2 trial due to funding issues, had relied upon data from 25 of the 38 patients in the trial to both generate and confirm the trial's hypothesis, and had interposed several unplanned interim analyses and comparisons of the interim data into the trial." (¶ 118) In addition, the paper disclosed that "[t]he P values were not adjusted for the unplanned interim analyses or for the multiple comparisons . . . because of the

exploratory nature of the study design with small sample size." (*Id.*) The CAC fails to allege any drop in the share price of the Company after this disclosure. The disclosure, therefore, cannot qualify as a corrective disclosure sufficient for the purposes of pleading loss causation. *See, e.g.*, *Lentell*, 396 F.3d at 175.

With respect to the second alleged disclosure, the CAC alleges that an October 19, 2011 article in the *TheStreet.com* served as a partial corrective disclosure, which resulted in a 6% drop in the price of the Company's stock. (¶¶ 148). As the CAC admits, the article "summarized for investors a 'plain English' explication" by an oncologist "of the [*Journal of Clinical Oncology*] manuscript and the statistical implications of the fact that Keryx had not adjusted the *P* values 'for the unplanned interim analyses or for the multiple comparisons' that it had made to the Phase 2 data." (*Id.*) In other words, the article contained observations about the Phase 2 clinical trial, which the author and the doctor developed through a review of previously released publicly available material. As a matter of law, this disclosure cannot serve as a partial corrective disclosure sufficient to satisfy the loss causation requirement. The Second Circuit has held, "[a] negative journalistic characterization of previously disclosed facts does not constitute a corrective disclosure of anything but the journalists' opinions." *In re Omnicom Group, Inc. Sec. Litig.*, 597 F.3d 501, 512 (2d Cir. 2010).

In *In re Omnicom Group, Inc*., the plaintiff alleged that information contained in a *Wall Street Journal* article constituted a partial corrective disclosure, which caused the market price of the company to drop. *See* 597 F.3d at 513. Examining the article, however, the Court described it as a "negative characterization" that contained only facts previously disclosed to the market. *See id*. at 513. Because the plaintiff had failed to show that the article contained any new information, the Court held it could not, as a matter of law, constitute a corrective disclosure.

See id. at 513. Here, the October 19, 2011 article in *TheStreet.com* contained a negative characterization of facts previously disclosed to the market on October 5, 2011, when the *Journal of Clinical Oncology* published its article on the Phase 2 trial. Therefore, the October 19, 2011 article in the *TheStreet.com* cannot constitute a corrective disclosure because it disclosed no new facts to the market.

A complaint may plead loss causation (1) by alleging, as examined above, that the market reacted negatively to a corrective disclosure, or (2) by alleging that defendant's misstatements concealed a risk that later materialized to cause the plaintiff's loss. *See In re Merrill Lynch & Co. Research Reports Sec. Litig.*, 568 F. Supp. 2d 349, 359 (S.D.N.Y. 2008). Tacitly admitting the failure to allege a sufficient corrective disclosure that would avoid dismissal here, the CAC also alleges that the "risk concealed by Defendants' repeated misleading statements materialized on April 2, 2012 upon the Company's announcement of perifosine's failed Phase 3 results." (¶ 152) The CAC alleges a 73% drop in Keryx's stock price following this announcement. (*Id.*) The CAC does not contain any allegations, however, that Defendants knew, but failed to disclose, the results of the Phase 3 trial prior to April 2, 2012. Similarly, the CAC does not allege that the Company misrepresented and/or omitted material facts with respect to the Phase 3 trial, which only came to light on April 2, 2012. Instead, the CAC alleges that Defendants repeatedly stated "how the purportedly positive results from the Phase 2" trial "provided a 'strong' basis for expecting the Phase 3 results to be successful . . . ." (¶ 64) Upon close examination of the statements quoted in the CAC, however, Defendants did no such thing. Defendants merely stated that "[t]he Phase 2 trial conducted in this setting provides strong rationale for the benefit of the perfosine/capecitabine combination in the treatment of advanced refractory colorectal cancer and we are extremely excited to initiate this Phase 3 registration trial

. . . ." (*Id.*) In any event, this statement is nothing more than "puffery and corporate optimism" that cannot be the basis for a federal securities claim. *See, e.g., Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004).

V. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court dismiss the CAC in its entirety[6] with prejudice.

Date: August 26, 2013

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[6] Because the CAC fails to plead a primary violation of Section 10(b), the Section 20(a) claim should also be dismissed with prejudice. *See, e.g., Aeterna Zentaris Inc.*, No. 12-Civ.-4711-PKC, 2013 WL 2399869, at *20 (S.D.N.Y. May 29, 2013); *Ross v. Lloyds Banking Group, PLC*, No. 11-Civ.-8530-PKC, 2012 WL 4891759, at *11 (S.D.N.Y. Oct. 16, 2012).